REMARKS:

Claims 1, 10 and 13 have been amended to state that the instant method has a rapid acquisition time of minutes, support for which may be found throughout the application, for example, at least on page 15, lines 12-13.

Claims 1, 3-6, 9-10, 12-19 and 21-23 were rejected under 35 USC 103(a) as unpatentable over Kenet.

In the above-referenced interview summary, it is stated that 'the claims read on Kenet if the control spectrum is obtained before the lesion occurs'.

Applicants respectfully note that Kenet does not teach taking a spectrum from a lesion portion and a control portion but rather Kenet teaches using multispectral digital photography 'to characterize and classify surface structure components and processes, and their temporal-spatial distributions, in particular, the depth of their subsurface extents' (US Patent 5,836,872, column 2, lines 18-21). Kenet states that the multispectral images are typically red, blue, green and infra-red photographs.

Furthermore, at column 20, lines 27-33, Kenet states 'once lesions on the anatomic surface are detected by the segmentation algorithms 320, their morphologic and spectral features are determined and represented as a set of quantitative parameters. For surfaces such as the skins [sic] quantitative descriptors of lesion asymmetry, border irregularity, color, diameter, elevation, and texture may be of clinical importance.'

Thus, Kenet teaches recording 'spectral features' of lesions only and does not teach or suggest comparison with an unaffected control portion of tissue as a step in diagnosis.

At column 25, lines 2-10, Kenet states that 'a multispectral color wheel using the multispectral generalization of the HIS color space transformation, described in pre-processing 316, may be used to plot generalized multispectral distributions of hue and saturation and to calculate statistics thereof. Multispectrally derived features, such as relative lesion depth and volume, may be computed using information derived from the subsurface reconstruction method described above in system function 318.'

As this section clearly indicates, Kenet does not teach or suggest spectral analysis of the lesion and comparison of this spectrum with a control spectrum but rather teaches analysis of the distribution of multispectral features.

It is again noted that Kenet at best teaches that it is 'worth a try' to determine if 'multispectral images' could be used to 'classify' skin lesions but provides no evidence that

this can be done nor does Kenet state what categories of lesions could possibly be identified. As discussed above, Kenet also teaches the use of 'multispectral images' which is clearly not the same as taking a spectrum from a skin portion containing a lesion.

This is clearly shown at column 25, lines 31-38 wherein Kenet states that 'given some a priori information about how morphologic and spectral features of pigmented cutaneous lesions correlate with microscopic pathologic features thereof, a classification method may be employed by the invention that incorporates this a priori information into a classification scheme that would estimate the probability that a given cutaneous lesion belonged to a particular pathological class or diagnosis.'

However, Kenet provides no teaching or suggestion as to exactly what this 'a priori information' is nor does Kenet provide any evidence or proof that this 'a priori information' derived from 'microscopic pathologic features' can in fact be used to classify a lesion to a particular pathological class or diagnosis, nor does Kenet even provide examples of what classes these might be.

Finally, at column 25, lines 50-59, Kenet states that 'once lesions on, or regions of, the anatomic surface are detected by the segmentation algorithm 320, their morphologic, spectral, or other features are determined and represented as a set of quantitative parameters 322. These quantitative parameters are stored in a database 326 along with the original and processed images, all acquisition and processing parameters, and clinical data provided by the patient and physician. Information in the database may be used for subsequent temporal comparison, tissue classification, or clinical decision making.'

This section further emphasizes that Kenet teaches recordation of statistical data derived from multispectral images as well as the multispectral images themselves on lesions only and then storing this information for comparison to the same lesion for changes over time (temporal comparison) or possibly classifying the lesion based on the unspecified 'a prior information on microscopic pathologic features' that Kenet theorizes may be used, discussed in greater detail above.

That is not applicants' invention. Applicants teach collecting a visible or near-IR light spectrum from a portion of the skin afflicted with the skin disease and comparing same to a spectrum from an unaffected control skin portion.

Kenet teaches the use of digital photos which are then segmented using a specific algorithm to locate lesions. Multispectral images of the lesion(s) are taken and stored in a database. Quantitative data from the images relating to lesion depth and volume are also

recorded for comparison at a later date. Kenet also theorizes that there may be a link between 'microscopic pathologic features' and data derived from morphological and 'spectral' analysis and that this could be used to classify lesions, but provides no teaching or suggestion as to what this 'a priori information' might be, nor any evidence that such a link does exist.

In summary, applicants' invention differs from Kenet's in several important ways which are reflected in the claims. Specifically, applicants' invention is based on the comparison of a visible or near-IR spectra taken from a skin lesion and a control tissue portion. Based on this comparison, the skin lesion is identified as dysplastic melanocytic nevi; banal nevi; lentigines; actinic keratoses; seborrheic keratoses; basal cell carcinoma; or malignant melanoma. As discussed in the earlier affidavit of Inventor Jackson, this allows for the skin lesion to be identified as possibly malignant or potentially malignant (actinic keratoses, basal cell carcinoma, dyplastic nevi) or benign (banal nevi, seborrheic keratoses actinic lentigines). Where the lesion is benign, no biopsy is necessary.

As discussed above, Kenet analyzes multispectral images for information on lesion substructure depth and volume. Only multispectral images of lesions are taken and this data is clearly considered as supporting evidence to be used in combination with the morphological data recorded by the digital photograph. As discussed above, Kenet hypothesizes that classification of skin lesions could be done if a link could be shown between 'microscopic pathologic features' and spectral and morphological data but as discussed above does not show that such a link exists nor does Kenet teach or suggest the exact nature of the 'microscopic pathologic features' or how they would be determined and/or measured.

It is also important to note that Kenet teaches comparison of lesions to lesions, either comparing the lesion to itself to detect changes over time or comparing the lesion of interest to lesions in a database of 'a priori information on microscopic pathologic features'. However, Kenet does not teach or suggest comparison to an unaffected control portion.

In the section entitled 'Response to Arguments' in the office action dated August 31, it is stated that 'any time period for which an analysis is performed could be measured in minutes'.

It is believed that the amendments to the claims clarify applicants' invention and distinguish their invention from Kenet. Specifically, it is held that one skilled in the art would understand that 'rapidly' refers to the fact that a lesion spectrum and a control spectrum are taken and compared contemporaneously, that is, during the same patient visit and the

analysis to identify the lesion as dysplastic melanocytic nevi; banal nevi; lentigines; actinic keratoses; seborrheic keratoses; basal cell carcinoma; or malignant melanoma is also done rapidly and does not rely on changes in substructure or lesion morphology over much longer periods of time as taught by Kenet.

Claims 7 and 20 were rejected under 35 USC 103(a) as unpatentable over Kenet and further in view of Jackson et al, Richards-Kortum et al or Soller et al.

It is believed that the amendments to the independent claims and the arguments forwarded above distinguish applicants' invention from Kenet and therefore overcome this objection as well.

Claim 8 was rejected under 35 USC 103(a) as unpatentable over Kenet in view of Haaland et al.

It is believed that the amendments to the independent claims and the arguments forwarded above distinguish applicants' invention from Kenet and therefore overcome this objection as well.

Further and more favorable consideration is respectfully requested.

Respectfully submitted

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